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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/007,700 | 11/30/2001 | Tongtong Wang | 210121.455C17 | 3322 |

500 7590 09/22/2003

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| EXAMINER |
|---|
| CHEN, SHIN LIN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/007,700 | WANG ET AL. | |
| | Examiner | Art Unit | |
| | Shin-Lin Chen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method for inducing an immune response in an animal with a composition comprising a polynucleotide that is at least 90% identical to SEQ ID No. 347, classifiable in classes 435 and 514, subclasses 320.1 and 44, respectively.

II. Claims 8, 10, 11 and 19-21, drawn to an isolated polynucleotide comprising the sequence as cited in the claims, a composition comprising said polynucleotide, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 536, 435 and 514, subclasses 23.5, 320.1 and 44, respectively.

III. Claims 9, 14, 15 and 19-21, drawn to an isolated polypeptide comprising an amino acid sequence as recited in the claims, a fusion protein comprising said polypeptide, a composition comprising said polypeptide, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 514, 424 and 530, subclasses 2, 192.1 and 350, respectively.

IV. Claims 12 and 19-21, drawn to an isolated antibody or an antigen-binding fragment thereof that specifically binds to a polypeptide of claim 9, a composition comprising said antibody, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 530 and 424, subclasses 387.1 and 130.1, respectively.

V. Claims 16, 22 and 23, drawn to an oligonucleotide that hybridizes to the sequence recited in the claim, a method for determining the presence of a cancer in a patient by

using said oligonucleotide, and a diagnostic kit containing said oligonucleotide, classifiable in classes 536 and 435, subclasses 24.3 and 6, 810, respectively.

VI. Claim 17, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with a polypeptide according to claim 9, classifiable in classes 514 and 435, subclasses 2 and 372.3, respectively.

VII. Claim 17, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with a polynucleotide according to claim 8, classifiable in classes 424 and 435, subclasses 93.21 and 372.3, respectively.

VIII. Claim 17, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with an antigen presenting cell that expresses a polynucleotide according to claim 8, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

IX. Claims 18-21 and 25, drawn to isolated T cells prepared by contacting T cells with polypeptide according to claim 9, a composition comprising said T cells, a method for stimulating an immune response in a patient, and a method for treating a cancer in a patient with said composition, classifiable in classes 514 and 435, subclasses 2 and 372.3, respectively.

X. Claims 18-21 and 25, drawn to isolated T cells prepared by contacting T cells with polynucleotide according to claim 8, a composition comprising said T cells, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 424 and 435, subclasses 93.21 and 372.3.

XI. Claims 18-21 and 25, drawn to isolated T cells prepared by contacting T cells with antigen presenting cells that express a polynucleotide according to claim 8, a composition comprising said T cells, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

XII. Claims 19-21, drawn to a composition comprising an antigen-presenting cell expressing the polypeptide according to claim 9, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 435 and 424, subclasses 372.2 and 184.1.

XIII. Claims 13 and 24, drawn to a method for determining the presence of a cancer in a patient by using a binding agent, such as an antibody, that binds to a tumor protein, and a diagnostic kit comprising said antibody, classified in class 435, subclasses 7.1 and 810.

Claims 19-21 link(s) inventions II-IV and IX-XII. Claim 17 links to inventions VI-VIII. Claims 18 and 25 links to inventions IX-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 17-21 and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Group I is distinct from groups II-XIII because they represent different and distinct DNA sequences derived from different genes. The chemical structures of different genes are different from each other and their gene product functions also differ from each other. Searches for those different gene sequences would not be coextensive. Thus, group I is patentably distinct from groups II-XIII.

Groups II-IV are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: polynucleotides, polypeptide and antibody. Search for polynucleotide does not require search for either polypeptide or antibody, search for polypeptide does not require search for antibody or polynucleotide. Since the classification for each is different, the search for each group would not be coextensive. They are not obvious variants and deemed patentably distinct.

Group XII is distinct from groups II-IV because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: antigen-presenting cells vs. polypeptides, polynucleotides and antibodies. They have different classifications and require separate search. They are not obvious variants and deemed patentably distinct.

Groups VI-VIII are distinct from each other because they are drawn to materially different methods using compositions having different chemical structures, physical properties

and biological functions, and requiring separate search: polypeptides, polynucleotides and antigen-presenting cells. Those methods differ at least in method steps, dosages and reagents used, schedules used, response variables, and criteria of success. They have different classifications and require separate search. They are not obvious variants and deemed patentably distinct. Similarly, groups IX-XI are distinct from each other for the same reasons as discussed above.

Groups VI-VIII are distinct from groups IX-XI because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. A method for stimulating and/or expanding T cells specific for a tumor protein and a method for stimulating an immune response or treating a cancer in a patient by using the proliferating T cells are different methods with different objectives, different reagents and/or dosages, different method steps and response variables. Thus, groups VI-VIII are patentably distinct from groups IX-XI and require separate search.

Groups V, VI-XI and XIII are distinct from each other because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. A method for stimulating and/or expanding T cells specific for a tumor protein, a method for stimulating an immune response or treating a caner in a patient by using the proliferating T cells, and a method for determining the presence of a cancer in a patient by using a binding agent, such as an antibody or an oligonucleotide, are different methods with different objectives, different reagents and/or dosages, different method steps and response variables. Thus, groups V, VI-XI and XIII

are patentably distinct from each other. They have different classifications and require separate search.

Groups V-XIII are distinct from groups II-IV because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages, schedules used, response variables, and criteria for success. A method for stimulating and/or expanding T cells specific for a tumor protein and a method for determining the presence of a cancer in a patient by using a binding agent, such as an antibody or an oligonucleotide, are different from a method for stimulating an immune response or treating a caner in a patient and they have different objectives, different reagents and/or dosages, different method steps and response variables. Similarly, a method of stimulating an immune response or treating a caner in a patient by using polynucleotides, polypeptides or antibodies is different and distinct from a method of stimulating an immune response or treating a caner in a patient by using an isolated T cell. Thus, groups V-XIII are patentably distinct from groups II-IV. They have different classifications and require separate search.

Upon election of a group from groups II-XIII, a further restriction is required as follows:

Since the SEQ ID Nos recited in the claims of the present application were isolated by a PCR-based subtraction of cDNA libraries prepared from human lung tumors and human normal cells, they represent different and distinct DNA sequences derived from different genes. The chemical structures of different genes are different from each other and their gene product functions also differ from each other. Thus, the SEQ ID Nos recited in the claims of the present

application are patentably distinct from each other and require separate search. Applicant is required to elect a **single** SEQ ID No. for consideration by examiner

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.